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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MANUEL MARQUEZ,
SAMANTHA M. MARQUEZ, and ANTONIO GARCIA[1]

Appeal 2015-007398
Application 12/726,158
Technology Center 1600

Before JEFFREY N. FREDMAN, TAWEN CHANG, and RYAN H. FLAX, *Administrative Patent Judges*.

CHANG, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to an artificial gland, which have been rejected as directed to non-statutory subject matter, lacking in written description, non-enabled, and anticipated or obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify the Real Party in Interest as the inventors Manuel Marquez and Samantha Marquez. (Appeal Br. 3.)

STATEMENT OF THE CASE

"Tissue and organ engineering are popular terms used to describe efforts to form complex living structures using cells as building blocks." (Spec. ¶ 3.) According to the Specification, "[m]ore sophisticated tissue structures are presently possible using scaffolding, which requires the use of a macro-scale material that can promote 3-dimensional cell organization into tissue by providing a surface for cell attachment and proliferation." (*Id.* at ¶ 6.) Further according to the Specification, the present invention provides a "micrometer-to-millimeter-scale artificial gland comprising a membrane of cellular material surrounding a reservoir comprising a bioreactor," which is "capable of being used to support the growth of organs and other biological material without the use of macro-scale scaffolds" and "can control the 3-dimensional arrangements of cells and subcellular systems in . . . a way that can mimic nature." (*Id.* at ¶ 18.)

Claims 1–5, 7, 8, 13, and 31–36 are on appeal. Claim 1 is illustrative and reproduced below:

> 1. An artificial gland comprising an independent unit for promoting biological activity, the independent unit consisting of an isolated product, the artificial gland further comprising:
> cells assembled in three dimensions in a component selected from the group consisting of a flow chamber, a microfluidic device, and an ink jet printer, the cells organized to form a membrane, the membrane configured to define an enclosed volume; and,
> a reservoir within the enclosed volume, the reservoir comprising a bio-reactor containing a product of activity of the cells.

(Appeal Br. 77 (Claims App'x).)

The Examiner rejects claims 1–4, 7, and 33–36 under 35 U.S.C. § 101 as being directed to non-patentable subject matter.[2] (Ans. 3.)

The Examiner rejects claims 1–5, 7, 8, and 13 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement.[3] (*Id.* at 5.)

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[2] There is some confusion as to which claims are subject to the rejection under 35 U.S.C. § 101. In the June 3, 2014 Office Action, the Examiner stated that "[c]laims ***1–7 and 31–36*** are rejected under 35 U.S.C. [§] 101 because . . . the cells of claims ***1, 2, 4, 7 and 31–36*** do not indicate the 'hand of man.'" (June 3, 2014 Office Action 2 (emphasis added).) In the Final Rejection, the Examiner states that "[c]laims ***1–4, 7, and 34–36*** are rejected under 35 U.S.C. [§] 101 because . . . the cells of claims ***1, 2, 4, 7 and 31–36*** do not indicate the 'hand of man' for reasons set forth in the office action mailed June 3, 2014." (Final Act. 2 (emphasis added).) In the Appeal Brief, Appellants stated that all of the claims, i.e., claims ***1–5, 7, 8, 13, and 31–36***, are rejected under 35 U.S.C. § 101 (Appeal Br. 29). In the Answer, the Examiner did not appear to have included any new ground of rejection or withdrawn the rejection of any claim under 35 U.S.C. § 101, but now states that "[c]laims ***1–4, 7 and 33–36*** remain rejected under 35 U.S.C. [§] 101." (Ans. 3 (emphasis added).) Finally, in the Response to Arguments section of the Answer, the Examiner states both that "[c]laims ***1–4, 7 and 33–36*** remain rejected under 35 U.S.C. [§] 101" and that "claims 31 and 33 are ***not*** rejected under 35 U.S.C. [§] 101." (*Id.* at 15 (emphasis added); *see also id.* at 20 (analyzing claims 33 and 34 under 35 U.S.C. § 101).) Taking all of the above into account, particularly the Examiner's explicit statement that claim 31 is not rejected under 35 U.S.C. § 101, the analysis of claims 33 and 34 under 35 U.S.C. § 101 in the Answer, and the corresponding lack of analysis of claims 31 and 32, we understand for purposes of this decision that the Examiner's 35 U.S.C. § 101 rejection applies to claims 1–4, 7, and 33–36.

[3] Our analysis does not change regardless of whether the Examiner's written description and enablement rejections are based upon 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph.

The Examiner rejects claims 1–5, 7, 8, 13, and 31–36 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement. (*Id.* at 7.)

The Examiner rejects claims 1, 2, 4, 7, 33, and 34 under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Zetter.[4] (*Id.* at 13.)

The Examiner rejects claims 1, 2, 4, 7, 33, and 34 under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Debnath.[5] (*Id.* at 14.)

The Examiner rejects claims 1, 2, 4, 7, and 33–36 under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Kirk,[6] as evidenced by Volvox Study Guide.[7] (*Id.*)

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[4] Bruce R. Zetter et al., *Expression of a high molecular weight cell surface glycoprotein (LETS protein) by preimplantation mouse embryos and teratocarcinoma stem cells*, 75 PROCEEDINGS NAT'L. ACAD. SCI. 2324 (1978).

[5] Jayanta Debnath et al., *Morphogenesis and oncogenesis of MCF-10A mammary epithelial acini grown in three-dimensional basement membrane cultures*, 30 METHODS 256 (2003).

[6] David L. Kirk, Quick Guide, *Volvox*, 14 CURRENT BIOLOGY R599 (2004).

[7] We were unable to locate citation information for the Volvox Study Guide in either the Answer or the Final Rejection. Nevertheless, the Volvox Study Guide is cited only as evidence of the size of the volvox spheroid, which we understand is relevant only to the limitation in claim 3 that "the artificial gland has a dimension not exceeding 500 microns." As Appellants did not separately argue claim 3, the Volvox Study Guide is not necessary to our decision.

The Examiner rejects claims 1, 2, 4, 5, and 33–36 under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Napolitano.[8] (*Id.* at 15.)

I.

Issue

The Examiner has rejected claims 1–4, 7, and 33–36 under 35 U.S.C. § 101 as being directed, without significantly more, to a judicial exception to patentable subject matter. The Examiner finds that the claims relate to

> an artificial gland that is an independent unit for promoting biological activity, the artificial gland comprising: cells assembled in three dimensions and organized to form a membrane, the membrane configured to define an enclosed volume; and, a reservoir within the enclosed volume, the reservoir comprising a bio-reactor containing a product of activity of the cells.

(Ans. 3.) The Examiner finds that the remaining limitations of the claims, such as cells being assembled "in a component selected from the group consisting of a flow chamber, a microfluidic device, and an ink jet printer," "relates to the method of making the gland" and "are not claimed to be part of the gland." (Final Act. 5.) Thus, the Examiner finds that such limitations do not impact the analysis with respect to 35 U.S.C. § 101. (*Id.*; *see also* Ans. 18.)

Based on the above, the Examiner finds that the artificial gland of the claims reads on "naturally occurring aggregates of cells" such as those

[8] Anthony P. Napolitano et al., *Dynamics of the Self-Assembly of Complex Cellular Aggregates on Micromolded Nonadhesive Hydrogels*, 13 TISSUE ENGINEERING 2087 (2007).

disclosed in Zetter, Debnath, and Kirk. (Ans. 3–4.) In particular, the Examiner finds that Zetter teaches

> a 4-day mouse blastocyst contain[ing] two distinct cell types: an outer layer of trophectoderm that encloses a fluid-filled cavity, the blastocoel, and the pluripotent [inner cell mass] ICM at one end of the blastocoel. As shown, the 4 day blastocyst is about 100 microns. The blastocyst comprises cells forming a membrane around a fluid filled cavity, the blastocoel, containing proteins secreted by the cells, and additional cells, the ICM.

(*Id.* at 4 (citations omitted).) The Examiner also finds that Debnath teaches

> the in vitro formation of mammary gland acini possessing a hollow luminal space surrounded by cells, containing milk protein secretion products from the cells. The acini is about 50 microns in diameter. The mammary gland acini is comprised of mammary epithelial cells surrounding a hollow, which would be air filled, center containing secreted milk proteins and tissue fluid.

(*Id.* (citations omitted).) Finally, the Examiner finds that Kirk teaches that

> volvox is a spherical multicellular green alga containing many small biflagellate somatic cells and non-motile gonidia, and moves by a rolling motion. The volvox spheroid contains within its core extracellular matrix and juvenile spheroids. The volvox spheroid is 350-500 microns in size. Thus, the volvox spheroid is composed of volvox cells that form a membrane surrounding a gel center that contains cells as well as secreted volvox proteins, the extracellular matrix. Volvox meets the limitations of the claims.

(*Id.* at 4–5 (citations omitted).)

Appellants contend that independent claims 31 and 33 do not recite cells and thus the Examiner's rationale with respect to the 35 U.S.C. § 101

rejection is inapplicable as to those and related claims.[9] (*Id.* at 30, 34.) With respect to the remaining claims, Appellants contend that the claims are not directed to natural products (Appeal Br. 29, 31), and that, in any event, the claims as a whole recite something significantly different than a natural product. (*Id.* at 32–38.)

Appellants do not separately argue claims 2–4 and 7. We thus limit our analysis to claims 1 and 33–36. The issue with respect to this rejection is whether the evidence of record supports the Examiner's conclusion that claims 1 and 33–36 are directed to non-patentable subject matter.

Fact

1. Zetter describes that, "[a]t the blastocyst stage (approximately 64 cells) [a mouse] embryo contains two distinct cell types: an outer layer of trophectoderm that encloses a fluid-filled cavity, the blastocoel, and the pluripotent [inner cell mass] ICM at one end of the blastocoel." (Zetter 2325, right column.)

2. Zetter describes flushing the mouse embryos by standard procedures from the oviduct or the uterus of a mouse. (Zetter 2324, right column.)

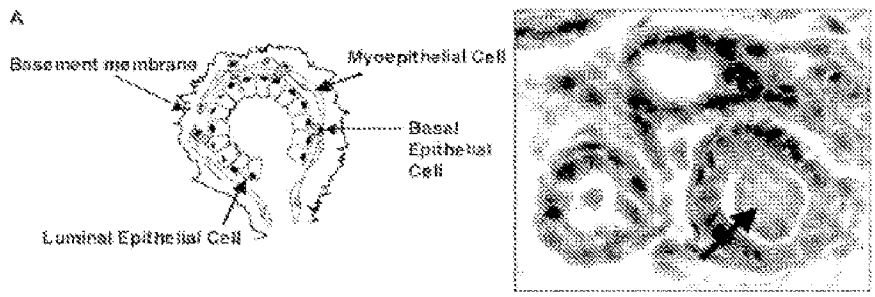
3. The Examiner finds that "[a]ny protein secreted by the trophoectoderm [sic] would . . . be expected to be found within the

[9] The Examiner has stated that claim 31 is not rejected under 35 U.S.C. § 101 and also provides no argument relating to claim 31 with respect to the 35 U.S.C. § 101 rejection. (Ans. 15.) Accordingly, we do not address Appellants' argument regarding claim 31 in the context of this rejection.

blastocoel fluid" and cites Dardik[10] as evidence that trophectoderm proteins are present in blastocoel fluid. (Ans. 30.)

4. Debnath teaches that "[g]landular epithelial cells, such as those in the mammary gland, have several distinguishing histological features including a polarized morphology, specialized cell-cell contacts, and attachment to an underlying basement membrane." (Debnath 256, left column.)

5. Fig. 1A of Debnath is excerpted below:



(Debnath Fig. 1A.) Fig. 1A of Debnath depicts a "[s]chematic (left) of a lobule from human mammary gland" and "[a] hematoxylin- and eosin-stained tissue section (right) of acini within human mammary tissue."[11] (*Id.* at Fig. 1A caption.) Debnath teaches that "mammary epithelium possesses a polarized architecture surrounding a hollow lumen, which is surrounded by an inner layer of luminal epithelial cells and an outer layer of myoepithelial

[10] The Examiner did not provide the full citation to Dardik. However, we understand that the Examiner's citation is to Alan Dardik et al., *Protein secretion by the mouse blastocyst: differences in the polypeptide composition secreted into the blastocoel and medium*, 45 BIOLOGY REPROD. 328 (1991).

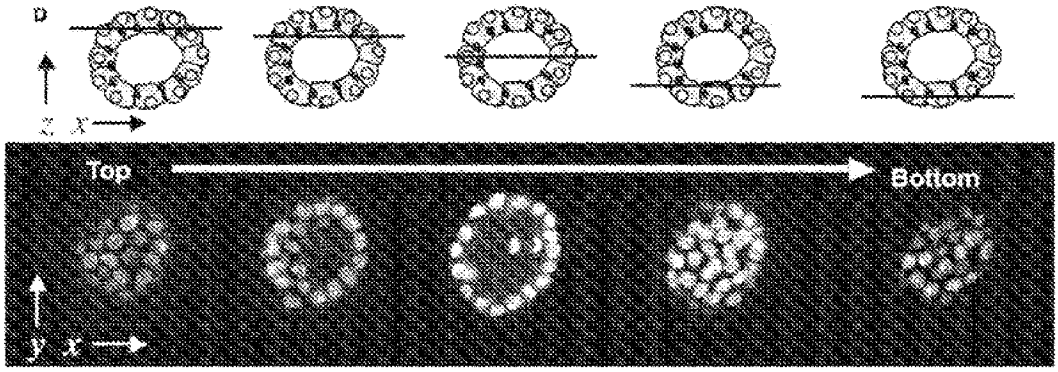
[11] Acini are epithelial cell-lined "pockets" within the mammary gland that can expand when filled with milk.

and basal epithelial cells," and further teaches that "the lumens of mammary acini in vivo often contain proteinaceous secretory material." (*Id.*)

6. Debnath teaches that "mammary epithelial cells grown in three dimensions recapitulate numerous features of breast epithelium in vivo, including the formation of acini-like spheroids with a hollow lumen, apicobasal polarization of cells making up these acini, the basal deposition of basement membrane components (collagen IV and laminin V), and, in some cases, the production of milk proteins." (Debnath 257, left column; *see also id.* at Abstract.)

7. Debnath teaches a specific method of growing mammary epithelial cells from the MCF-10A cell line in three-dimensional culture. (*Id.* at 257, left column (describing MCF-10A cell line); 261–263 (method of growing three-dimensional culture).)

8. Figure 5D of Debnath is excerpted below:



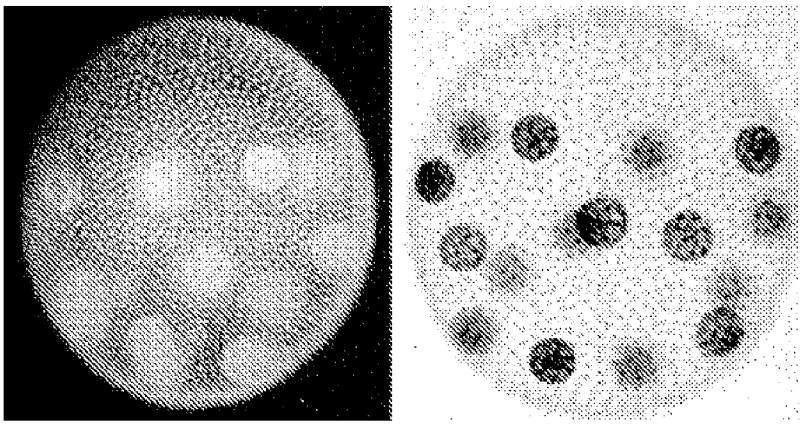
(*Id.* at Fig. 5D.) Figure 5D of Debnath depicts "[s]erial confocal cross sections (x-y axis) through a Day 15 MCF-10A acinus. The schematic diagrams overlying each section illustrate the relative position of the optical section with respect to the z axis." (*Id.* at Fig. 5D caption.)

9. Kirk discloses that volvox "is a spherical multicellular green algae, which contains many small biflagellate somatic cells and a few large, non-motile reproductive cells called gonidia." (Kirk R599, column 1.)

10. Kirk discloses that, during asexual reproduction, "mature gonidium initiates . . . cleavage divisions" to create a "[a] fully cleaved embryo contain[ing] all of the cells of both types that will be present in an adult" but that is inside out, which then undergoes inversion to turn right-side-out. (*Id.* at R599, column 2.)

11. Kirk discloses that, "[f]ollowing inversion, both the adult spheroid and the juvenile spheroids within it increase in size (without further cell division) by depositing large quantities of a glycoprotein-based extracellular matrix. Part way through the expansion phase, the juveniles digest their way out of the parental matrix and become free-swimming." (*Id.*)

12. The sole figure in Kirk is excerpted below:



(Kirk R599.) The figure in Kirk shows "[d]arkfield (left) and brightfield (right) micrographs of a . . . spheroid of *Volvox carteri* containing many small somatic cells and a few large, asexual reproductive cells called gonidia." (*Id.*)

Principles of Law

Patentable Subject Matter

Natural phenomena, including naturally occurring organisms, are not patentable. *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1335–1336 (Fed. Cir. 2014).

In *Funk Brothers*, "bacteria produced by the laboratory methods of culture are placed in a powder or liquid base and packaged for sale to and use by agriculturists in the inoculation of the seeds of leguminous plants." *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 129 (1948). The Supreme Court concluded that such a mixture of bacteria was not patent eligible: "The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none." *Id.* at 130; *see also In re Roslin Institute (Edinburgh)*, 750 F.3d at 1336 (explaining that "while the method of selecting the strains of bacteria [in *Funk Brothers*] might have been patent eligible, the natural organism itself—the mixture of bacteria—was unpatentable because its 'qualities are the work of nature' unaltered by the hand of man") (citation omitted).

In *Chakrabarty*, the Supreme Court found that, in contrast to the mixture of bacteria in *Funk Brothers*, "the patentee has produced a new bacterium *with markedly different characteristics from any found in nature* and one having the potential for significant utility." *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (emphasis added).

In *Myriad*, the Supreme Court held that "extensive effort alone is insufficient to satisfy the demands of § 101." *Association for Molecular*

Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2118 (2013). The Court further found that Myriad's claims, which relate to isolated DNA of genes that may be examined to determine a person's risk of developing breast cancer, *id.* at 2112–2113, were not "saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule": "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA." *Id.* at 2118.

Finally, in *Roslin*, the Federal Circuit applied the above Supreme Court case law and found that claims to a "live-born clone" of a donor mammal are not directed to patent-eligible subject matter. *Roslin*, 750 F.3d at 1337. In particular, although patent applicants contended that "copies (clones) are eligible for protection because they are 'the product of human ingenuity' and not 'nature's handiwork, but [their] own,'" the Federal Circuit found that a clone is not patentable because it is "an exact genetic replica" of the donor mammal and "does not possess 'markedly different characteristics from any [farm animals] found in nature.'" *Id.* (brackets in original and citations omitted).

Product-by-Process Claims

"The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (citation omitted).

Analysis

Claim 1

In light of Supreme Court and Federal Circuit precedent, we agree with the Examiner that claim 1 is invalid as being directed to non-patentable subject matter.

We begin by noting that claim 1 is a claim to a product, i.e., an artificial gland. Thus, while claim 1 recites that cells are "assembled in three dimensions in a component selected from the group consisting of a flow chamber, a microfluidic device, and an ink jet printer," the patentability of the claim does not depend on such methods of production. *In re Thorpe*, 777 F.2d at 697. Given the above, and as also discussed below in Sections IV and VI, we agree with the Examiner that claim 1 reads on natural products, specifically the mouse blastocysts described in Zetter and the volvox algae described in Kirk.[12] (FF1–3, 9–11.)

[12] The Examiner finds that claim 1 also reads on the mammary gland acini described in Debnath, which the Examiner finds to be another example of naturally occurring structure that cannot be distinguished from the structure of claim 1. (Ans. 4.) We are not convinced. Claim 1 requires cells organized to form a membrane, which in turn define an enclosed volume. Although Debnath does disclose acini-like spheroids that reads on claim 1, as discussed further below in Section V, such spheroids are not naturally occurring, but rather grown in three-dimensional culture in vitro. (FF6–FF8.) In contrast, as depicted in Debnath Figure 1A (left), it is not clear that the epithelial cells of the naturally occurring mammary gland acini define an "enclosed" volume, because the epithelial cells do not appear to completely surround the "lumen." (FF5.) Thus, we do not rely on Debnath in affirming the Examiner's rejection of claim 1 under 35 U.S.C. § 101. *Cf. In re Bush*, 296 F.2d 491, 496 (CCPA 1961) (the Board may rely on less than all of the references relied upon by Examiner).

Appellants rely on the 2014 Interim Guidance in arguing that the claims are patentable.[13] We address these arguments below.

Appellants first argue that the claims are patentable because they are directed to a manufacture and composition of matter and because they recite "artificial assembly . . . of cells" that are "assembled in a man-made device." (Appeal Br. 29, 31–32.) As already discussed, the specific process by which the cells are assembled does not confer patentability, because claim 1 is directed to a product. Given that claim 1 is a product claim, we are also not persuaded by Appellants' argument in view of *Myriad* and particularly *Roslin*. In both of those cases, the claimed products—an isolated DNA and a cloned mammal, respectively—are produced only after significant human intervention. The isolated DNA of *Myriad*, for instance, required "sever[ing] chemical bonds and thereby creat[ing] a nonnaturally occurring molecule." *Myriad*, 133 S. Ct. at 2118. Likewise, the cloned mammal in *Roslin* would not have existed without human involvement. Indeed, the method resulting in the clones claimed in *Roslin* "constituted a breakthrough in scientific discovery." *Roslin*, 750 F.3d at 1334. The claims in both of these cases have nevertheless been held to be directed to patent ineligible products of nature, because they do not possess "markedly different characteristics" from products found in nature. *Id.* at 1337 (citation omitted); *Myriad*, 133 S. Ct. at 2117.

Appellants next argue that, even if the claims were considered to be directed to a "natural product," they are patentable because they recite as a

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[13] *2014 Interim Guidance on Patent Subject Matter Eligibility*, 79 Fed. Reg. 74,618 (Dec. 16, 2014), available at https://www.federalregister.gov/articles/2014/12/16/2014-29414/2014-interim-guidance-on-patent-subject-matter-eligibility.

whole something significantly different than the natural product. (Appeal Br. 32–38.) Appellants first contend that the Examiner already admitted that the claimed artificial gland is "***structurally different*** from a naturally occurring gland." (*Id.* at 32–33.) We are not convinced. As the Examiner points out, Zetter and Kirk are not directed to naturally occurring glands as the term gland is conventionally understood. (Ans. 19.) Thus, the Examiner's statement is far from an admission that the blastocysts in Zetter and the volvox algae described in Kirk are structurally different from the claimed artificial gland.

Appellants also argue that the claims "require a structure that is an isolated product existing as an independent unit" as well as a reservoir/bioreactor containing a cell activity product, and that "claim limitations involving 'independent unit' and 'isolated product' are not met by any product found in nature." (Appeal Br. 34–35, 36–37.) We are not persuaded. Both Zetter's blastocysts and the volvox described in Kirk are independent units that may be isolated. (FF2, FF12.) Furthermore, the Supreme Court found in *Myriad* that isolated DNA are not patent eligible, even though such isolated DNA are not found in nature. *Myriad*, 133 S. Ct. at 2118.

Appellants next argue that, "[i]mplicit in this requirement [that cells be assembled into a membrane in a component selected from the group consisting of a flow chamber, a microfluidic device, and an ink jet printer,] is [a requirement] that the cells . . . be structurally fit in order to survive assembly in these machines." (Appeal Br. 35.) We are not persuaded. Appellants provide no persuasive evidence to support the claim that the cells of the claimed artificial gland are more "structurally fit" than those in the

cellular aggregates disclosed in Zetter and Kirk. *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence."). Furthermore, Appellants do not suggest that the assembly devices render the cells more structurally fit, and neither the claims nor the Specification suggests any method of treating the cells to render it sufficiently "structurally fit" to survive in machine assembly. Thus, the structural integrity Appellants suggest to be a distinguishing characteristic is nevertheless natural.

Appellants reiterate that the claims require cells be assembled into a membrane in a man-made device and argue that, "[e]ven if the assembly machines are not considered as imbuing any structure to the artificial gland," they impose "meaningful limits on claim scope that avoid substantially foreclosing the use of any natural product." (Appeal Br. 35–36.) As already discussed, this argument is not persuasive in light of *Myriad* and particularly *Roslin*.

Finally, with respect to whether a "[c]laim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field," Appellants contend that the claims "require a unique combination of materials to create a unique product not before seen or available to enable unique research capabilities and unique treatment possibilities." (Appeal Br. 38.) Such generic attorney argument, without supporting evidence, does not suffice to render the claims patent eligible. *In re Pearson*, 494 F.2d at 1405.

Claims 33 and 34

Claims 33 and 34 require the claimed artificial gland to comprise "*components of a cell* assembled in three dimensions and organized to form

a membrane." (Appeal Br. 97 (Claims App'x) (emphasis added).) Appellants contend that claims 33 and 34 do not recite cells and thus the Examiner's rationale with respect to the 35 U.S.C. § 101 rejection is inapplicable as to these claims. (*Id.* at 30, 34.) The Examiner responds that "an artificial gland produced by a membrane of cells[] is produced by a membrane of cellular components," because "[c]laims 33 and 34 do not require the cell components to be isolated." (Ans. 20.)

We find Appellants have the better argument. The Specification describes the embodiment relating to claims 33 and 34 as one in which "components of a cell are used *instead of* cells." (Spec. ¶ 59.) Thus, we are not persuaded that an artificial gland comprising "components of a cell . . . organized to form a membrane" reads on aggregates of intact cells such as the blastocyst and volvox described respectively in Zetter and Kirk.

Claim 35

Appellants argue that claim 35 is not directed towards a product of nature because no naturally occurring product anticipates or renders obvious the artificial gland recited in claim 35. (Appeal Br. 30.) We are not persuaded because we find that volvox, an algae that occurs in nature, anticipates claim 35, as further discussed below in connection with the rejection of claim 35 under 35 U.S.C. § 102 as anticipated by Kirk.

Claim 36

Appellants argue that claim 36 is not directed towards a product of nature because no naturally occurring product anticipates or renders obvious the artificial gland recited in claim 36. (Appeal Br. 30.) We find Appellants have the better argument. Although the Examiner contends that Zetter, Debnath, and Kirk all disclose "naturally occurring structures that cannot be

distinguished from the structure in claims 1–4, 7, and 33–36," the Examiner has provided no citation to the cited references wherein a specified type of "organized algae micro-colony" is naturally found within a volume enclosed by a membrane formed of cells, as required by claim 36.

Accordingly, we affirm the Examiner's rejection of claims 1 and 35 and reverse the Examiner's rejection of claims 33, 34, and 36 under 35 U.S.C. § 101. Claims 2–4 and 7, which were not separately argued, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

II.

Issue

The Examiner has rejected claims 1–5, 7, 8, and 13 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. Citing to paragraph 45 of the Specification, the Examiner finds the Specification states "the artificial gland is an independent unit and an isolated product," in contrast to the artificial gland as claimed, which is "made up of an independent unit and something else, where the independent unit consists of an isolated product, the product being undefined." (Ans. 6.)

Appellants appear to agree that the Specification "explains that the artificial gland is the 'isolated product' and is an 'independent unit.'" (Appeal Br. 40.) Appellants argue, however, that "in view of the explanation in the description, a reasonable interpretation of claim 1 would require that the claimed 'artificial gland' is made up as an 'independent unit,' which because of the transitional phrase 'comprising' is an essential, (not an optional) feature" and which further "may not be other than an 'isolated product.'" (*Id.* at 40–41; Reply Br. 32.) Appellants contend that

the Examiner disregarded the "plain meaning of 'independent unit' as a state of being and not as a thing or component in plain view of the express provision in the specification." (Reply Br. 34.) Appellants further argue that "[t]he adequacy of the written description was attested to by a third party declaration." (Appeal Br. 42.)

Appellants do not separately argue the claims, and we limit our analysis to claim 1. The issue with respect to this rejection is whether the evidence of record supports the Examiner's conclusion that the Specification does not describe an artificial gland "comprising" an independent unit.

Findings of Fact

13. The Specification discloses "[a]n artificial gland . . . in the form of an independent unit for promoting biological activity." (Spec. ¶ 11.)

14. The Specification states,

> In its simplest form, the first artificial gland embodiment (100) is essentially first cells (110) surrounding a first reservoir (105) and is an independent micro-scale unit for promoting biological activity.
>
> For all of the embodiments, the artificial gland, as an independent unit, is an isolated product that can be assembled into tissue, organs, or other biological supportive material. Preferably, the artificial gland is in the micron size range of about 10-500 microns. However, larger embodiments up to a centimeter and beyond in diameter are theoretically possible.

(Spec. ¶¶ 44–45.)

Principles of Law

A description adequate to satisfy 35 U.S.C. § 112, first paragraph, must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." In

> other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.

Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citation omitted, alteration in original).

The Examiner "bears the initial burden . . . of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

> Insofar as the written description requirement is concerned, that burden is discharged by "presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.". . . If the applicant claims embodiments of the invention that are completely outside the scope of the specification, then the examiner . . . need only establish this fact to make out a prima facie case.

In re Alton, 76 F.3d 1168, 1175 (Fed. Cir. 1996) (citation omitted).

Analysis

As set forth above, claim 1 recites an artificial gland "comprising an independent unit for promoting biological activity," the independent unit "consisting of an isolated product," and the artificial gland "further comprising" cells organized to form a membrane defining an enclosed volume and a reservoir within the enclosed volume comprising a bio-reactor containing a product of activity of the cells.

We agree with the Examiner that claim 1 encompasses embodiments outside of the scope of the Specification. In particular, the Specification only describes an artificial gland that is an independent unit and an isolated product. (FF13, FF14.) In using the open transitional phrase "comprising,"

however, claim 1 encompasses artificial glands that *include* an independent unit that is an isolated product, but need not themselves *be* independent units or isolated products.

We note but are not convinced by Appellants' argument that the Examiner's construction of the claim is unreasonable. (Appeal Br. 40–41; Reply Br. 31–34.) While claims are read in light of the Specification, "[c]laim language itself sets the claim scope." *Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc.*, 246 F.3d 1336, 1347 (Fed. Cir. 2001). "When a patent claim uses the word 'comprising' as its transitional phrase," as claim 1 does here, "the use of 'comprising' creates a presumption that the body of the claim is open. In the parlance of patent law, the transition 'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements." *Id.* at 1348. The Examiner's construction of the claim is consistent with this general tenet of claim construction.

We are likewise unpersuaded by Appellants' argument that "[t]he adequacy of the written description was attested to by a third party declaration" because the Cheng Declaration[14] allegedly "point[ed] to peer[] reviewed scientific reports on the manufacture and use of the artificial gland to be supportive of the operability, functionality and usefulness of the claimed artificial gland." (Appeal Br. 42.) As an initial matter, the "operability, functionality and usefulness" of the claimed invention does not

[14] Declaration of Zhengdong Cheng under 37 C.F.R. § 1.132 (Oct. 25, 2012) ("Cheng Declaration"). The Cheng Declaration is not paginated. Therefore, all reference to page numbers in the Cheng Declaration refer to page numbers as if the Cheng Declaration was numbered consecutively beginning with the first page.

show that the "*disclosure* of the application . . . reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms.*, 598 F.3d at 1351 (emphasis added). Furthermore, the generic statement in the Cheng Declaration was not supported by analysis of how any of the cited reports is supportive of the operability, functionality and usefulness of the claimed invention. Opinions on ultimate legal issues are not entitled to weight absent supporting evidence. *In re Reuter*, 670 F.2d 1015, 1023 (CCPA 1981) (expert's opinion on ultimate legal issue entitled to no weight).

Accordingly, we affirm the Examiner's rejection of claim 1 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. Claims 2–5, 7, 8, and 13, which were not separately argued, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

III.

Issue

The Examiner has rejected claims 1–5, 7, 8, 13, and 31–36, because "[t]he specification does not provide guidance for producing or using the claimed artificial gland." (Ans. 8.) The Examiner finds that a gland is "an organ or a tissue that produces and secretes proteins, enzymes or hormones . . . either constitutively or regulated by a signal from outside the gland." (*Id.*) The Examiner finds that the claims are not enabled because the claimed structure "lacks the mechanism for either constitutive release or regulated release" and because the Specification fails to provide guidance for obtaining such release. (*Id.* at 9–10.) The Examiner finds that there is no enablement commensurate with the full scope of the claims, because the

claimed reservoir can be water, gas, or gel, but the Specification "provides no guidance as to the type of gas that would solubilize proteins, enzymes or hormones." (*Id.*) The Examiner further finds that the claims are not enabled because the Specification fails to provide guidance as to how to overcome any immune response to the claimed structure or how to obtain organ regeneration either in vivo or in vitro through use of the claimed structure. (*Id.* at 10.) Finally, the Examiner finds that claims 33 and 34 further lacks enablement because the Specification "does not provide guidance for the formation of an artificial gland that contains a membrane of cellular components," [15] as required by these claims, or how such a gland may be used "for drug testing, tumor biology and organ/tissue regeneration or replacement" as disclosed in the Specification. (*Id.* at 11–12.)

With respect to claims 33 and 34,[16] Appellants argue that the Examiner erroneously assumes without basis that self-aggregation to form a membrane is cell-dependent. (Appeal Br. 44–45.) Appellants did not address the enablement rejection of the remaining claims in the Appeal Brief, but argue in the Reply Brief that the enablement requirement is satisfied with respect to the term "artificial gland" because of "the potential of a group of cells making up the shell to deliver the contents of the

[15] Both the Examiner and Appellants direct their arguments relating to formation of an artificial gland using components of a cell to claims 31 and 32. (Ans. 11–12; Appeal Br. 44–45.) As the Examiner points out in response to Appellants' arguments, however, such arguments appear properly directed towards claims 33 and 34. (Ans. 26.) Appellants did not dispute this characterization of the arguments in the Reply Brief; accordingly, we analyze these arguments as though they are directed towards claims 33 and 34.

[16] *See supra* note 13.

reservoir" and in view of an expert declaration[17] that purportedly "point[s] to peer[] reviewed scientific reports on the manufacture and use of the artificial gland [that are] supportive of the operability, functionality and usefulness of the claimed artificial gland." (Reply Br. 34–36 (citing Appeal Br. 41–43).) Appellants also argue that the Examiner's construction of the term "gland" is unduly narrow. (*Id.* at 35–36.) With respect to the Examiner's argument that the enablement is not commensurate with the scope of the claims because the Specification does not enable a "reservoir" that is a gas, Appellants argue that the Specification teaches a method of making the artificial gland wherein a gas is introduced into a microchannel, and further argue that there is no requirement that the claimed reservoir "solubilizes proteins" as suggested by the Examiner. (*Id.* at 36–37.) Finally, Appellants argue that the Examiner has cited no evidence that undue experimentation would be needed to implement the invention as claimed. (*Id.* at 37.)

The issue with respect to this rejection is whether the evidence of records supports the Examiner's conclusion that the Specification does not enable a skilled artisan to make and use the claimed artificial gland.

Findings of Fact

15. The Specification states that an artificial gland is

> a "living capsule" with a biomembrane (tissue) shell and a unique core that acts as container or reservoir. . . . The reservoir is a bio-reactor capable of containing a product of activity of the cells. The reservoir preferably comprises a gas, a liquid, or a gel and preferably also contains nanoparticles, a buffer, a surfactant, and, a gel precursor. The reservoir may

[17] Appellants do not reference a specific expert declaration; however, we assume Appellants to be referring to the previously discussed Cheng Declaration.

> also contain cells. Nanoparticles may also surround the artificial gland to form a protective coating.

(Spec. ¶ 11; *see also id.* at ¶¶ 18–19, 26.)

16. The Specification states that "[t]he contents of the bio-reactor preferably include a substance comprising a fluid in the form of a gas, liquid, gel, or a combination of these." (*Id.* at ¶ 48.)

17. The Specification states that "the artificial gland is useful for biological tissue and organ repair and replacement and stem cell engineering and biotechnology applications." (*Id.* at ¶ 2; *see also id.* at ¶¶ 3, 7, 13–16, 21, 27–28, 53, 168, 169, 173–175, 214, 220.) In particular, the Specification states that the artificial gland "is capable of being used to support the growth of organs and other biological material without the use of macro-scale scaffolds" and "can control the 3-dimensional arrangements of cells and subcellular systems in such a way that can mimic nature." (*Id.* at ¶ 18; *see also id.* at ¶¶ 20–24, 28 (application to 3-D in vitro cell cultures), 52 ("[s]hape variability [of artificial gland] . . . broadens the parameter-space for the design of any type of artificial tissue, and can help to direct strategies for all types of tissue engineering"), 56, 149.) The Specification further indicates that claimed artificial glands have applications in the treatment of diseases. (*Id.* at ¶¶ 56, 171, 178–180, 189, 194, 207, 209–210.)

18. The Specification states that "[the] artificial glands with a membrane of cells and a central reservoir . . . create opportunities to trigger events that can lead to . . . vehicles for food and pharmaceutical applications." (*Id.* at ¶ 13; *see also id.* at ¶¶ 21, 23, 25 ("new means for manipulating controlled releases or absorptions supporting biological activity," "tuning rheological or optical properties of cosmetics, foods, or

other fluids," and "functionaliz[ation] for a specific biological tasking"), 149–152.)

19. The Specification indicates that the claimed artificial glands have applications in drug or therapy screening and in modeling disease states for study. (*Id.* at ¶¶ 56, 170, 172, 176, 211–213.)

20. The Specification states,

> An alternative embodiment of the artificial gland uses the same configuration and components as described above, except that biological units are used instead of cells. The biological units form a membrane. . . . Biological units are similar in that they perform a biological activity that produces products, but they may not be classified as living. Biological units include fungi, algae, spores, pollen, yeast, bacteria, and viruses.
>
> An alternative embodiment of the artificial gland uses the same configuration and components as described above, except that components of a cell are used instead of cells. The components of a cell form a membrane assembled in three dimensions. . . . Components of a cell are similar in that they perform a biological activity that produces products, but they are not classified as living. Examples of components of a cell are: enzymes, prions, hormones, growth factors, Tumor Necrosis Factor-alpha, Tumor Necrosis Factor-beta, cytokines, interleukins, albumin-scavengers, polyclonal-anti-bodies, monoclonal-anti-bodies, immunoglobulines, protease enzymes, lysosomes, vesicles, cell membranes, rough endoplasmic reticulums, smooth endoplasmic reticulums, mitochondria, ribosomic ribonucleic acid, transference ribonucleic acid, deoxyribonucleic acid, mitrotubules, endocrine cells, and human T-cells, fatty acids, beta-OH-butirate, acetoacetate, polycations, poly L lisine, ornithine, chitosan, oligoelements, genes, chloroplasts, chlorophyll, glucidic elements.

(*Id.* at ¶¶ 58–59.)

Principles of Law

> Section 112 requires that the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation . . . . [*S*]*ee also In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) ("[T]he specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed.") . . . .

Invitrogen Corp. v. Clontech Labs. Inc., 429 F.3d 1052, 1070–71 (Fed. Cir. 2005) (citation and internal quotation marks omitted).

> Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

"[T]he enablement requirement of § 112 incorporates the utility requirement of § 101." *In re Fisher*, 421 F.3d 1365, 1378 (Fed. Cir. 2005). Courts "have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.* at 1371.

> [A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the "substantial" utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.

Id.

To satisfy "the 'specific' utility requirement, an application must disclose a use which is not so vague as to be meaningless. . . . Thus, in

addition to providing a 'substantial' utility, an asserted use must show that th[e] claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.* "Nebulous" expressions such as "biological activity" or "biological properties," and "obscure" expressions such as "useful for technical and pharmaceutical purposes" do not suffice to provide specific utility. *Id.*

"Enablement, or utility, is determined as of the application filing date." *In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995). "It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file." *In re Glass*, 492 F.2d 1228, 1232 (CCPA 1974).

Analysis

Appellants address only claims 33 and 34 in its Appeal Brief with respect to the enablement rejection; accordingly, we limit our analysis of this rejection to these two claims and summarily affirm the Examiner's enablement rejection of claims 1–5, 7, 8, 13, 31, 32, 35, and 36.[18]

[18] Appellants make additional arguments that are applicable to the other rejected claims in their Reply Brief. These arguments are waived, however, because they were not presented in the opening brief, thereby denying the Board the benefit of the Examiner's response, and no showing of good cause was made by Appellants to explain why the late argument should be considered by the Board. *See* 37 C.F.R. § 41.41(b)(2); *Cf. Optivus Technology, Inc. v. Ion Beam Applications S.A.*, 469 F.3d 978, 989 (Fed. Cir. 2006) (argument raised for the first time in the Reply Brief that could have been raised in the opening brief is waived).

Claim 33 requires the claimed artificial gland to comprise "components of a cell assembled in three dimensions and organized to form a membrane." (Appeal Br. 97 (Claims App'x).) Claim 34, which depends from claim 33, clarifies that the components of the cell encompassed within claims 33 and 34 include, among others:

> enzymes, prions, hormones, growth factors, Tumor Necrosis Factor-alpha, Tumor Necrosis Factor-beta, cytokines, interleukins, albumin-scavengers, polyclonal-anti-bodies, monoclonal-anti-bodies, immunoglobulines [sic], protease enzymes, lysosomes, vesicles, cell membranes, rough endoplasmic reticulums, smooth endoplasmic reticulums, mitochondria, ribosomic ribonucleic acid, transference ribonucleic acid, deoxyribonucleic acid, mitrotubules [sic microtubules ?], endocrine cells, and human T-cells, fatty acids, beta-OH-butirate [sic butyrate], aceto acetate, polycations, poly L lisine [sic lysine], ornithine, chitosan, oligoelements, genes, chloroplasts, chlorophyll, [and] glucidic elements.

(*Id.* at 97–98.)

We agree with the Examiner that claims 33 and 34 fail to satisfy the enablement requirement because the Specification "does not provide guidance for the formation of an artificial gland that contains a membrane of cellular components" or how such a gland may be used "for drug testing, tumor biology and organ/tissue regeneration or replacement" as disclosed in the Specification. (Ans. 11–12.) We note that there are no working examples of an artificial gland comprising a membrane of cellular components,[19] and only minimal, if any, other direction or guidance in the

[19] While the Specification discloses "a method of artificial gland production implemented as a proof of concept," the method uses cells (specifically yeast cells) rather than cell components. (Spec. ¶ 77; *see also id.* at ¶ 215 (stating that "[a]n artificial gland constructed with a fibroblast membrane has been constructed for testing the invention"), ¶ 169 (stating that "[a]rtificial micro-

Specification regarding how to make a membrane composed from other cellular components. *In re Wands*, 858 F.2d at 737 (describing factors to be considered in determining enablement). Furthermore, none of the prior art cited by the Examiner describes such a membrane of cellular components, and the scope of the claims 33 and 34 is extremely broad, encompassing components as divergent as genes and chlorophyll. *Id.*

Appellants argue that the Specification "explains that the mechanism forming the artificial gland using *components of a cell* operates in the same way as for cells," "indicates that the mechanism employed is non-cellular dependent," and "explains that self-aggregation may be aided by the ability to control non-cellular-related physical factors associated with the assembly environment." (Appeal Br. 44–45.) We are not persuaded. While we understand Appellants assert that the same basic factors of, e.g., minimization of interfacial energy and electrostatic interaction, affect the formation of a membrane composed of cellular components as well as that composed of cells, the Specification provides no support that such factors would affect cells and all the claimed cellular components ***in the same way so as to lead to creation of a membrane***. Neither does the Specification provide any guidance on how such factors should be adjusted in view of the differences between cells and the many different types of cellular components claimed.

Appellants further argue that "[t]he embodiments involving components of cells may be used in many of the same research activities as

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glands were suspended separately in a concentrated phosphate buffered saline solution [and] subsequently printed as a kind of 'ink' onto several []biopapers made from soy agar and collagen gel").)

other embodiments." (*Id.* at 45–46.) We are likewise not persuaded. Appellants' broad statements regarding potential use of the claimed artificial glands (FF17–19) do not describe the "specific and substantial" utility needed to satisfy the enablement requirement. Generic statements that the claimed artificial gland is useful for "biological tissue and organ repair and replacement," "stem cell engineering," "biotechnology applications," "treatment of diseases," "vehicles for food and pharmaceutical applications," or "applications in drug or therapy screening and in modeling disease states for study" are too vague to provide ***specific*** utility. *In re Fisher*, 421 F.3d at 1371.

Similarly, these statements do not provide substantial utility because they suggest that the claimed artificial gland "may prove useful at some future date after further research," but do not show that it is "useful to the public as disclosed in its current form." *Id.* The Specification states, for example, that the claimed artificial gland "holds ***the potential*** to play a vital role in tissue engineering, stem cell engineering, synthetic biology, and in the design of multicellular vehicles for food and pharmaceutical applications." (Spec. ¶ 21 (emphasis added).)

Finally, while working examples are not ***necessary*** to satisfy enablement, they are desirable in complex technologies, and we note that the Specification provides no such examples of using the claimed artificial gland. *In re Strahilevitz*, 668 F.2d 1229, 1232 (CCPA 1982) (working examples desirable but not necessary); *In re Fisher*, 421 F.3d at 1377 (finding lack of specific and substantial utility because "[applicant's] laundry list of uses, like the terms 'biological activity' or 'biological properties' alleged in *Kirk*, are nebulous, especially in the absence of any

data demonstrating the claimed [inventions] were actually put to the alleged uses").

Accordingly, we affirm the Examiner's rejection of claims 1–5, 7, 8, 13, and 31–36 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement.

IV.

Issue

The Examiner rejects claims 1, 2, 4, 7, 33, and 34 under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Zetter. As discussed above, the Examiner finds that Zetter teaches a mouse blastocyst containing an outer layer of trophectoderm cells enclosing a fluid-filled cavity (the blastocoel), with the pluripotent ICM at one end of the blastocoel. (Ans. 13.) The Examiner finds that "[n]o distinction between the mouse blastocyst taught by Zetter and the claimed invention [exists,]" because Zetter's blastocyst "comprises cells forming a membrane around a fluid filled cavity, the blastocoel, containing proteins secreted by the cells, [together with] additional cells, the ICM." (*Id.* at 13–14.)

Appellants contend that Zetter does not teach that the fluid-filled cavity of the blastocyst contains any product of the trophectoderm. (Appeal Br. 47.) Appellants also contend that the blastocyst disclosed in Zetter is not "an independent unit" or "an isolated product." (*Id.* at 49–50.) Appellants further contend that Zetter does not teach an artificial gland with the structural limitations implicit in the claimed method of assembly. (*Id.* at 51–52.) Citing *Chakrabarty*, the Specification, various news articles, and the

Cheng Declaration, Appellants further argue that the invention "involves a manufactured or artificial gland with 'markedly different characteristics'" than natural products, including "robust tissue structural characteristics that enable many uses not found in nature." (*Id.* at 53–56.) Finally, Appellants contend that Zetter does not disclose a membrane made of "components of a cell" as required by claims 33 and 34.[20] (*Id.* at 48.)

Appellants do not separately argue claims 2, 4, and 7, and we therefore limit our analysis to claims 1, 33, and 34. The issue with respect to this rejection is whether the evidence of record supports the Examiner's conclusion that claims 1, 33, and 34 are anticipated or rendered obvious by Zetter.

Analysis

Claim 1

As an initial matter, claim 1 is directed to a product (i.e., an artificial gland), even though it also recites limitations regarding the process used to create such a product. As noted earlier, "[t]he patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d at 697. Zetter discloses all of the structural limitations of claim 1; accordingly, the evidence of record supports the Examiner's finding that Zetter anticipates claim 1.

[20] Appellants also argue that Zetter does not disclose the volvox algae and algae micro-colony required by claims 35 and 36. (Appeal Br. 49.) The Examiner has removed claims 35 and 36 from the anticipation rejection over Zetter. (Ans. 30.) Accordingly, we do not address Appellants' arguments regarding claims 35 and 36 with respect to this rejection.

Zetter teaches a mouse blastocyst containing an outer layer of trophectoderm cells enclosing a fluid-filled cavity (the blastocoel), with the pluripotent ICM at one end of the blastocoel. (FF1.) Thus, Zetter teaches cells assembled in three dimensions and organized to form a membrane (i.e., the trophectoderm), with the membrane configured to define an enclosed volume (i.e., the blastocoel). Furthermore, the blastocyte is an independent unit and an isolated product within the broadest reasonable interpretation of those terms, as Zetter describes isolating them from the oviduct or uterus of the mouse. (FF2.) Given the substantial identity between the structure described in Zetter and the claimed structure, we also find that the Examiner has established a prima facie case that the blastocoel contains a product of the activity of the cells in the trophectoderm. *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (explaining that "when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not"). Neither have Appellants disputed in the Reply Brief the Examiner's citation to Dardik as evidence that the blastocoel in Zetter's blastocyst contains trophectoderm proteins. (Ans. 30.)

Zetter studies the expression of LETS protein in mouse embryos. (Zetter Abstract.) Appellants contend that Zetter teaches that the LETS protein is ***not*** produced by the trophectoderm and that Zetter thus does not disclose "a reservoir . . . containing a product of activity of the cells." (Appeal Br. 47–48.) We are not persuaded because the Examiner finds that the blastocoel contains other, non-LETS proteins that are produced by the trophectoderm (Ans. 30), and, as discussed, Appellants have not disputed this finding in the Reply Brief.

Appellants also contend that Zetter does not teach an artificial gland with the structural limitations achieved by the claimed method of assembly. (*See generally* Appeal Br. 50–56.) Appellants first argue that the Examiner is inconsistent in simultaneously finding that "***the artificial gland claimed cannot be distinguished from a naturally occurring gland***" and that "[t]he present claims are not enabled because it is ***structurally dissimilar from a naturally occurring gland*** in that the structure lacks the mechanism for either constitutive release or regulated release." (*Id.* at 50.) We are not persuaded. As the Examiner points out, regardless of whether Zetter's blastocyst or the claimed structure is referred to as a "gland" and whether each may be considered structurally similar to a "naturally occurring gland," the significant point for purposes of the anticipation rejection is that Zetter discloses all of the ***structural*** limitations recited ***in the claims***. (Ans. 32.)

Neither are we convinced by Appellants' reliance on *Chakrabarty*, the Specification, various news articles, the Cheng Declaration, and attorney argument in contending that the invention "involves a manufactured or artificial gland with 'markedly different characteristics'" than natural products, including "robust tissue structural characteristics that enable many uses not found in nature." (Appeal Br. 53–56.) As further discussed below, while we agree that claim 1 may be patentable over Zetter if the method of production recited in the claim in fact results in structural differences, Appellants have not provided persuasive evidence that such structural differences exist.[21]

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[21] For this reason, Appellants' citation to *Chakrabarty* is unavailing. The artificial, genetically engineered microorganism in *Chakrabarty* was genetically distinct (i.e., structurally different) from the naturally occurring microorganism. *Chakrabarty*, 447 U.S. at 305, 309–310.

With respect to Appellants' argument that "the limitation specifying how the cells are assembled . . . is an implicit structural limitation because qualifying cells must be structurally viable to withstand the relatively fast acting assembly mechanism," we note that "[a]ttorney's argument in a brief cannot take the place of evidence." *In re Pearson*, 494 F.2d at 1405. For the same reason, we are not persuaded by Appellants' citation to the Specification regarding the ability of the claimed gland to "eliminate[] the need for a macro-scale tissue-shaping scaffold" and argument in the brief that "[n]o natural product has tissue structural characteristics that eliminate the need for a scaffold and such characteristics are only manifest if the manufactured object is both an independent unit and an isolated product." (Appeal Br. 54.)

Neither do the cited news articles and the Cheng Declaration provide evidence of any structural difference between the claimed artificial gland and Zetter's blastocyst. The news articles provide generic descriptions of "celloidosomes," which Appellants contend are the subject of the claims. Likewise, while the Cheng Declaration states that "[f]ungi, [a]lgae, [b]acteria and also a diverse group of mammalian cells . . . can be 'self-assembled' on gas-liquid interfaces of microbubbles, to form stable micro-core/shell tissues as described . . . in [the] patent application" (Cheng Decl. 2), and that "the artificial gland produced with algal and bacterial cells do form membranous (tissue and/or biofilm) structure and . . . secrete products of the cells from and into the core (reservoir) when used in vitro" (*id.* at 4),

such statements do not support Appellants' contention that the resulting artificial gland differs ***structurally*** from Zetter's blastocyst.[22]

Finally, we note, but are not persuaded by, Appellants' argument that the blastocyst disclosed in Zetter is not "an independent unit" or "an isolated product." (Appeal Br. 49–50.) As already discussed above, the blastocyst described in Zetter is isolated from the oviduct or uterus of the mouse. (FF2.)

Claims 33 and 34

With respect to claims 33 and 34, we find Appellants to have the better argument. As discussed earlier, these claims require "*components* of a cell" assembled in three dimensions and organized to form a membrane. (Appeal Br. 97 (Claims App'x; emphasis added).) The Examiner argues that claims 33 and 34 read on intact trophectoderm cells surrounding blastocoel fluid because "there is no requirement the components be isolated" and trophectoderm cells are made of cell components. (Ans. 30.) As also discussed above, however, the Specification describes the embodiment as one in which "components of a cell are used *instead of* cells." (Spec. ¶ 59 (emphasis added).) Thus, we are not persuaded that the limitation "components of a cell . . . organized to form a membrane" reads on a membrane formed from intact cells.

Accordingly, we affirm the Examiner's rejection of claim 1 as anticipated by Zetter but reverse the rejection of claims 33 and 34 on this

[22] As already discussed, opinions in the Cheng Declaration on ultimate legal issues, such as the statement that "the claimed artificial gland [is] a unique innovation," are not entitled to weight absent supporting evidence. *In re Reuter*, 670 F.2d at 1023.

ground. Claims 2, 4, and 7, which were not separately argued, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

V.

Issue

The Examiner rejects claims 1, 2, 4, 7, 33 and 34 under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Debnath. The Examiner finds that

> Debnath teaches the in vitro formation of mammary gland acini possessing a hollow luminal space surrounded by cells, containing milk protein secretion products from the cells. The acini are about 50 microns in diameter. The mammary gland acini is comprised of mammary epithelial cells surrounding a hollow, which would be air filled, . . . containing secreted milk proteins and tissue fluid. No distinction [exists] between the mammary gland acini taught by Debnath and the claimed invention. Thus, Debnath anticipates or makes obvious the claimed invention.

(Ans. 14 (citations omitted).)

Relying on essentially the same citations and arguments they relied on with respect to the rejection over Zetter, Appellants contend that Debnath does not teach an "artificial" gland and does not teach the structural limitations implicit in the claimed method of assembly. (Appeal Br. 66–71.) Appellants further argue that Debnath does not teach "a cellular membrane surrounding a reservoir that contains a product of activity of the cells of the membrane." (Appeal Br. 64–65.) Finally, Appellants contend that claim 33 does not recite membrane formed from cells and that the Examiner's

rationale as to anticipation by or obviousness over Debnath is thus inapplicable as to this claim.[23] (*Id.* at 63; Reply Br. 38–39.)

Appellants do not separately argue claims 2, 4, and 7, and we limit our analysis to claims 1, 33, and 34. The issue with respect to this rejection is whether the evidence of record supports the Examiner's conclusion that claims 1, 33, and 34 are anticipated or rendered obvious by Debnath.

Analysis

Claim 1

The evidence of record supports the Examiner's finding that Debnath anticipates claim 1. Debnath discloses a method of growing mammary epithelial cells from the MCF-10A cell line in three-dimensional culture. (FF7.) Debnath teaches that mammary epithelial cells grown in three dimensions form "acini-like spheroids with a hollow lumen." (FF6, FF8.) Accordingly, Debnath teaches cells assembled in three dimensions and organized to form a membrane (i.e., the outer cellular layer of the acini-like spheroid), with the membrane configured to define an enclosed volume (i.e., the hollow lumen). Furthermore, the acini-like spheroid is an independent unit and an isolated product within the broadest reasonable interpretation of those terms. (FF8 (depicting confocal cross sections of an individual acini-like spheroid).) Given the substantial identity between the structure described in Debnath and the claimed structure, we also find that the Examiner has established a prima facie case that the lumen of the acini-like

[23] Claim 34 depends from claim 33; thus, we address claims 33 and 34 together. Appellants makes similar arguments with respect to claim 31. (Appeal Br. 63.) However, the Examiner does not appear to have rejected claim 31 over Debnath, and we do not address arguments relating to claim 31 here.

spheroid contains a product of the activity of the cells. *In re Spada*, 911 F.2d at 708. In addition, Debnath teaches that "the lumens of mammary acini in vivo often contain proteinaceous secretory material" and further teaches that, at least in some cases, mammary epithelial cells grown in three dimensions produces milk proteins. (FF5, FF6.)

As they do with Zetter and relying on essentially the same citations to *Chakrabarty*, the Specification, various news articles, and the Cheng Declaration, Appellants contend that Debnath does not teach an artificial gland having the structural limitations implicit in the claimed method of assembly. (Appeal Br. 66–67.) These arguments are not persuasive for similar reasons as those discussed above with respect to the rejection over Zetter. Furthermore, Appellants do not explain why Debnath's cells grown in culture would not be considered "artificial" rather than a "natural product." (*Id.* at 66.)

As further discussed below, we are also not persuaded by Appellants' arguments that "[t]he human mammary tissue shown in Debnath Fig. 1A is not an encircling cellular membrane," that Debnath's acini lumens are not reservoirs within the meaning of the claim, and that Debnath does not teach "a cellular membrane surrounding a reservoir that contains a product of activity of the cells of the membrane." (*Id.* at 64–65.)

While Appellants argue that Debnath's Figure 1A does not show an encircling membrane, Figure 5, which provides "[r]epresentative confocal microscopic imaging of MCF-10A acini," shows that the mammary epithelial cells do in fact form a sphere that completely enclose the lumen when they are grown in three-dimensional culture. (FF8.) For the same reason, Appellants' citation to Merriam-Webster for the definition of lumen,

and the corresponding argument that a lumen is "a tubular cavity" and thus not a "reservoir enclosed by a cellular membrane" is unavailing. Appellants have not pointed out a structural difference between the lumen disclosed in, e.g., Fig. 5 of Debnath, and the reservoir recited in claim 1 and described in the Specification. (*See also* Spec. ¶ 47 ("The shape of th[e] configuration [of membrane formed from a plurality of cells] may be spherical, spheroidal, discoid, cylindrical, tubular or any other three-dimensional shape that physically defines an internal micro-scale volume.").)

Finally, to the extent Appellants are making a separate argument that Debnath does not disclose secretion products in the acini lumen that are "products of activity of the cells" forming the membrane, we disagree for the reasons already discussed: Debnath disclose a structure substantially similar to the claimed structure, and further teaches that "the lumens of mammary acini in vivo often contain proteinaceous secretory material" and that, at least in some cases, mammary epithelial cells grown in three dimensions produces milk proteins. (FF5, FF6.) In sum, the Examiner has demonstrated "sound basis for believing that the products of the applicant and the prior art are the same," and Appellants have not met the burden of showing that they are not. *In re Spada*, 91 F.2d at 708.

Claims 33 and 34

We find Appellants to have the better argument for claims 33 and 34, for the same reason as discussed above with respect to Zetter.

Accordingly, we affirm the Examiner's rejection of claim 1 as anticipated by Debnath but reverse the rejection of claims 33 and 34 on this ground. Claims 2, 4, and 7, which were not separately argued, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

VI.

Issue

The Examiner rejects claims 1, 2, 4, 7, and 33–36 under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Kirk, as evidenced by Volvox Study Guide. The Examiner finds that

> Kirk teaches volvox is a spherical multicellular green alga containing many small biflagellate somatic cells and non-motile gonidia, and moves by a rolling motion. The volvox spheroid contains within its core extracellular matrix and juvenile spheroids. [As evidenced by the Volvox Study Guide,] [t]he volvox spheroid is 350-500 microns in size. Thus, the volvox spheroid is composed of volvox cells that form a membrane surrounding a gel center that contains cells as well as secreted volvox proteins, the extracellular matrix. Volvox meets the limitations of the claims. No distinction [exists] between the Volvox taught by Kirk and the claimed invention. Thus, Kirk anticipates or makes obvious the claimed invention.

(Ans. 14–15 (citations omitted).)

Appellants contend that Kirk does not teach "a 'membrane' of volvox cells formed to create a reservoir as specified for claim[] 32."[24] (Appeal Br. 58.) With respect to claims 33 and 34, Appellants argue that Kirk does not disclose a membrane made of components of a cell. (*Id.* at 59.) With respect to claims 35 and 36, Appellants further argue that Kirk does not disclose a volvox algae or algae micro-colony within any reservoir formed by a membrane. (*Id.*) In the Reply Brief, Appellants further argue that Kirk does not disclose "a membrane formed of cells in machinery in a particular

[24] The Examiner does not appear to have rejected claim 32 over Kirk. We thus understand Appellants to be referring to claim 1 in this statement.

manner and that once formed are an isolated, independent unit," as required by claim 1. (Reply Br. 41.)

Appellants do not separately argue claims 2, 4, and 7. We therefore limit our analysis to claims 1 and 33–36. The issue with respect to this rejection is whether the evidence of record supports the Examiner's conclusion that claims 1 and 33–36 are anticipated or rendered obvious by Kirk.

Analysis

Claim 1

We find that the Examiner has established a prima facie case of anticipation of claim 1 in view of Kirk. Kirk teaches that volvox is a spherical multicellular algae that contains many small somatic cells and a few large non-motile reproductive cells. (FF9.) Kirk teaches that following asexual reproduction adult volvox comprises an outer layer of cells surrounding an enclosed volume containing juvenile volvox spheroids and glycoprotein-based extracellular matrix deposited by the volvox. (FF10–12.) Accordingly, Kirk teaches the volvox as comprising cells assembled in three dimensions and organized to form a membrane, with the membrane configured to define an enclosed volume. Furthermore, the volvox is an independent unit and an isolated product within the broadest reasonable interpretation of those terms. (FF12 (figure depicting a spheroid of *Volvox carteri*); *see also* FF9–FF11.) Finally, Kirk discloses that the enclosed volume contains a product of the activity of the membrane of cells, namely the glycoprotein-based extracellular matrix. (FF11.)

Appellants contend that Kirk teaches composition of volvox cells, not "a 'membrane' of volvox cells formed to create a reservoir as specified for

claim[] 32."[25] (Appeal Br. 58.) In particular, Appellants contend that "applicants' ***membrane*** (outer shell) must be made of more than one cell, not simply confine other cells within the outer shell," and "Kirk has no teaching that the outer structure of the volvox cell is multi-cellular." (*Id.*) Applicants' apparent argument is that Kirk discloses the volvox as a single cell containing many somatic cells and a few larger reproductive cells. (*Id.*) We are unpersuaded by this strained reading of Kirk's disclosure, which also contradicts Appellants' own description of the volvox in the Specification:

> Volvox algae, or simply volvox, is one of the best-known chlorophytes and is the most developed in a series of genera that form spherical colonies. ***Each mature volvox colony is composed of numerous flagellate cells . . . , up to 50,000 in total, and embedded in the surface of a hollow sphere*** or coenobium containing an extracellular matrix made of a gelatinous glycoprotein.

(Spec. ¶ 143.)

In the Reply Brief, Appellants argue for the first time that Kirk does not disclose "a membrane formed of cells in machinery in a particular manner and that once formed are an isolated, independent unit," as required by claim 1. (Reply Br. 41.) Appellants have waived this argument since it was not presented for the first time in the opening Appeal Brief. *Ex parte Borden*, 93 USPQ2d 1473, 1473–74 (BPAI 2010) ("informative"[26]) (absent a showing of good cause, the Board is not required to address an argument newly presented in the reply brief that could have been presented in the principal brief on appeal). In any event, as already discussed, a

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[25] The Examiner does not appear to have rejected claim 32 over Kirk. We thus understand Appellants to be referring to claim 1 in this statement.
[26] Designated as an "Informative Opinion" at http://www.uspto.gov/ip/boards/bpai/decisions/inform/index.jsp.

volvox is an isolated, independent unit, and furthermore "[t]he patentability of a product does not depend on its method of production." *In re Thorpe*, 777 F.2d at 697.

Claims 33 and 34

We find Appellants to have the better argument for claims 33 and 34, for the same reason as discussed above with respect to Zetter.

Claim 35

With respect to claim 35, Appellants argue that Kirk does not disclose a volvox algae within any reservoir formed by a membrane. (Appeal Br. 59.) We are not convinced. Claim 35 recites an artificial gland comprising "cells assembled in three dimensions and organized to form a membrane . . . defining an enclosed micro-scale volume," where "[the] reservoir within the enclosed micro-scale volume . . . comprise[s] volvox algae." (*Id.* at 98 (Claims App'x).) Kirk discloses that, following asexual reproduction, the juvenile volvox spheroids are contained within the adult spheroid until they "digest their way out of the parental matrix and become free-swimming." (FF11.) Thus, Kirk discloses volvox algae (i.e., the junior volvox spheroids) within a reservoir formed by a membrane of the adult volvox, which is in turn formed of multiple cells as discussed above.

Claim 36

With respect to claim 36, Appellants further argue that Kirk does not disclose a claimed algae micro-colony within any reservoir formed by a membrane. (Appeal Br. 59.) We find Appellants have the better argument. Claim 36 requires an artificial gland comprising "cells assembled in three dimensions and organized to form a membrane . . . defining an enclosed micro-scale volume," where "[the] reservoir within the enclosed micro-scale

volume . . . comprise[s] an organized algae micro-colony selected from the group consisting of diatoms, cyanobacteria, pediastrum, hydrodictyon, chlorella, paramecium bursania, Haematococcus pluvialis, spirogyra, mougeotia and zygnema." (*Id.* at 98–99 (Claims App'x).) The Examiner has not explained how Kirk discloses or renders obvious a reservoir comprising an algae micro-colony selected from the recited species.

Accordingly, we affirm the Examiner's rejection of claims 1 and 35 as anticipated by Kirk, but reverse the rejection of claims 33, 34, and 36 on this ground. Claims 2, 4, and 7, which were not separately argued, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

VI.

Issue

The Examiner rejects claims 1, 2, 4, 5, and 33–36 under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Napolitano. The Examiner finds that "Napolitano teaches a hydrogel core surround[ed] by fibroblast cells or fibroblast and endothelial cells . . . . Hydrogel is a nanoparticle[;] thus, the reservoir comprises nanoparticles. Thus, Napolitano clearly anticipates the claimed invention." (Ans. 15 (citations omitted).)

Appellants contend that Napolitano teaches "[a] spheroid of cells formed in the bottom of recesses of a gel," which Appellants argue is "a completely different structure than cells 'organized to form a membrane . . . to define an enclosed volume,' as specified in applicants' claim 1." (Appeal Br. 61.) Appellants also argue that Napolitano does not disclose the spheroid containing "a product of activity of the cells forming that spheroid." (*Id.*) Appellants argue that the Examiner's finding of

anticipation with respect to Napolitano fails to cite all of the limitations of claims 1, 2, 4, and 5. (*Id.*) With respect to claims 33 and 34, Appellants argue that Napolitano does not disclose "a membrane assembled from 'components of a cell.'" (*Id.* at 62.) With respect to claims 35 and 36, Appellants argue that Napolitano does not disclose a volvox algae or an algae micro-colony within the alleged reservoir. (*Id.*)

The issue with respect to this rejection is whether the evidence of record supports the Examiner's conclusion that Napolitano anticipates or renders obvious claims 1, 2, 4, 5, and 33–36.

Analysis

We find Appellants to have the better argument. The Examiner argues that Napolitano anticipates and/or render obvious the claims because it teaches "a hydrogel core surround by fibroblast cells or fibroblast and endothelial cells." (Ans. 15 (citations omitted).)

As Appellants point out, however, Napolitano teaches self-assembled cellular aggregates that form, e.g., spheroids in the bottom of the recess of a gel. (Appeal Br. 61; *see, e.g.*, Napolitano Abstract; 2089, left column; Figs. 1 and 2.) The Examiner has not explained how such spheroids would contain a hydrogel core given that they form in a *recess* of the gel.

In response to Appellants' argument, the Examiner argues that "there is no evidence in Napolitano that the spheres did not enclose a defined volume" and that "Napolitano teaches in the 200 μm wells expansion [of the cell aggregate] in the horizontal dimension was physically constrained by the hydrogel." (Ans. 42 (citations omitted).) We are not persuaded. First, Napolitano describes spheroids containing, for instance, a normal human fibroblast (NHF) core coated with human umbilical vein endothelial cells

(HUVECs). (Napolitano Abstract.) Thus, it is not clear that Napolitano discloses a "membrane" of cells that defines an "enclosed volume," much less a hydrogel core, rather than a solid spheroid of cells. In addition, given that Napolitano's spheroid cell aggregates are formed in the hydrogel well, it is unsurprising that they are constrained by the well size. The Examiner has not explained, however, how such constraint suggests that the spheroid contains a hydrogel core.

With respect to claims 33–36, we further agree with Appellants that the Examiner has not shown how Napolitano disclose "components of a cell assembled in three dimensions and organized to form a membrane," as required by claims 33 and 34, or a reservoir within an enclosed volume comprising volvox algae or an organized algae micro-colony, as required respectively by claims 35 and 36. Neither has the Examiner provided a response to Appellants' arguments with respect to these claims.

Accordingly, we reverse the Examiner's rejection of claims 1, 2, 4, 5, and 33–36 as anticipated by Napolitano. Because the Examiner has not articulated any separate rationale why the above-discussed claim limitations are rendered obvious by Napolitano, we also reverse the Examiner's rejection of claims 1, 2, 4, 5, and 33–36 as obvious over Napolitano.

SUMMARY

With respect to the rejection under 35 U.S.C. § 101, we affirm the rejection of claims 1–4, 7, and 35 and reverse the rejection of claims 33, 34, and 36.

With respect to the rejection under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, for failure to comply with the written

description requirement, we affirm the Examiner's rejection of claims 1–5, 7, 8, and 13.

With respect to the rejection under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, for failure to comply with the enablement requirement, we affirm the Examiner's rejection of claims 1–5, 7, 8, 13, and 31–36.

With respect to the rejection under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Zetter, we affirm the Examiner's rejection of claims 1, 2, 4, and 7 and reverse the Examiner's rejection of claims 33 and 34.

With respect to the rejection under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Debnath, we affirm the Examiner's rejection of claims 1, 2, 4, and 7 and reverse the Examiner's rejection of claims 33 and 34.

With respect to the rejection under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Kirk, we affirm the Examiner's rejection of claims 1, 2, 4, 7, and 35 and reverse the Examiner's rejection of claims 33, 34, and 36.

We reverse the Examiner's rejection of claims 1, 2, 4, 5, and 33–36 under pre-AIA 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. § 103(a) as obvious over, Napolitano.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED